

- C.1  
cont.
- b) applying a means for adjusting the viscosity of the medium until a gel with an apparent viscosity in the range 25 to 90 Pa.s at a shear rate of  $1\text{s}^{-1}$  is reached;
  - c) allowing crystal growth;
  - d) applying a means for adjusting the viscosity of the medium until a fluid with an apparent viscosity less than 25 Pa.s at a shear rate of  $1\text{s}^{-1}$  is reached; and
  - e) harvesting the crystals.

26(New). A crystallisation process as claimed in claim 25, wherein the means for adjusting the viscosity of the medium is temperature change, ultrasound, thixotropy, electro-rheology, mechanical shear, chemical additive, or pH change.

27(New). A crystallisation process as claimed in claim 26, wherein the means for adjusting the viscosity of the medium is pH change.

28(New). A crystallisation process as claimed in claim 25, wherein the medium is an aqueous solution of a Carbomer.

29(New). A crystallisation process as claimed in claim 25, wherein the substance to be crystallised is lactose, lactose monohydrate, salbutamol sulphate or ipratropium bromide.

30(New). A crystallisation process as claimed in claim 25, wherein the crystals are harvested by means of collection by filtration.

31(New). A crystallisation process as claimed in claim 25, wherein the process comprises:

- a) dissolving the substance to be crystallised in an aqueous solution of a medium wherein the viscosity of the medium is pH-dependent;

- b) adjusting the pH of the medium until a gel with an apparent viscosity in the range 25 to 90 Pa.s at a shear rate of  $1\text{s}^{-1}$  is reached;
- c) allowing crystal growth;
- d) adjusting the pH of the medium until a fluid with an apparent viscosity less than 25 Pa.s at a shear rate of  $1\text{s}^{-1}$  is reached; and
- e) harvesting the crystals.

32(New). A process as claimed in claim 31, wherein the medium is an aqueous solution of a Carbomer.

33(New). A crystallisation process as claimed in claim 25, wherein the substance to be crystallised is fluticasone propionate or salmeterol xinafoate.

34(New). Lactose monohydrate crystals obtained according to the process as claimed in claim 25.

35(New). Salbutamol sulphate, oxitropium bromide or ipratropium bromide crystals obtained according to the process as claimed in claim 25.

36(New). Fluticasone propionate or salmeterol xinafoate crystals obtained according to the process as claimed in claim 25.

37(New). A pharmaceutical formulation for administration by inhalation comprising lactose monohydrate crystals as claimed in claim 34 and/or salbutamol sulphate or ipratropium bromide crystals.

38(New). A pharmaceutical formulation for administration by inhalation comprising lactose monohydrate crystals as claimed in claim 34 and/or fluticasone propionate or salmeterol xinafoate crystals.

39(New). A crystallisation process as claimed in claim 25, wherein the substance to be crystallised is lactose monohydrate and the crystallised lactose monohydrate has an elongation ratio of  $1.58 \pm 0.33$  and a size in the range of 63 to 90  $\mu\text{m}$ .

40(New). A lactose monohydrate according to claim 34, having an elongation ratio  $1.58 \pm 0.33$  and a size in the range of 63 to 90  $\mu\text{m}$ .

41(New). Lactose monohydrate according to claim 34, having an elongation ratio of from 1.55 -2.20.